Section 3

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ACTICHROME® Heparin (anti-fIIa)
Heparin Assay (per 21CFR864.7525)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013637

Submitted by:
American Diagnostica Inc.
222 Railroad Avenue
Greenwich, CT 06830
Phone: 203 661-0000
Fax: 203 661-7784

Contact:
Clare Santulli
Field Trial Coordinator
Phone: 203 661-0000

Summary Revised
March 21, 2002

Name of the Device:
ACTICHROME® Heparin (anti-fIIa)
Product No. 820

Classification:
864.7525 Heparin Assay, Class II
Product Code KFF

Predicate Device:
Spectrolyse® Heparin (anti-IIa) K972209

Intended Use:
ACTICHROME® Heparin (anti-fIIa) is a chromogenic assay intended for the quantitative determination of therapeutic heparin in human plasma by measurement of factor IIa (thrombin) inhibition. The Electra 900C® was used to determine performance data.

Summary of Substantial Equivalence:
ACTICHROME Heparin (anti-fIIa) kit is substantially equivalent to the commercially available predicate device, Spectrolyse® Heparin (anti-IIa), manufactured by Biopool International, Ventura, CA, in performance and intended use.

Summary of Performance Data:

Method Comparison
Method comparison studies versus the predicate device were performed with one lot of ACTICHROME Heparin (anti-fIIa). The regression statistics in Table 1 indicate a positive correlation between the ACTICHROME Heparin (anti-fIIa) assay and the predicate device.

Table 1: Correlation (Y= ACTICHROME, X= predicate device)

ACTICHROME Heparin (anti-fIIa)	N	Regression Equation	R	Sy.x (ng/ml)	Sample Range (ng/ml)
Lot 010	88	Y=0.845X+.027	0.967	0.03	0.02-0.71
Lot 010	32	Y=0.764X+.032	0.917	0.05	0.00-0.55

Precision
Precision studies evaluated intra-assay and inter-assay variability with 2 control samples run in replicates of 4 over 20 runs (N=80 per control) and with two control samples run in replicates of 4 over 10 runs (N=40 per control), respectively.

Table 2a: Precision N=80

ACTICHROME Heparin (anti-IIa) Lot 010	Mean (USP/ml)	Intra-Assay CV%	Inter-Assay CV%
Hepanorm Control 6	0.42	4.7	7.6
Hepanorm Control 3	0.23	10.8	9.6

Table 2a: Precision N=40

ACTICHROME Heparin (anti-IIa) Lot 010	Mean (USP/ml)	Intra-Assay CV%	Inter-Assay CV%
Control Plasma spiked with 0.5 U/ml Heparin	0.51	3.8	8.5
Control Plasma spiked with 0.25 U/ml Heparin	0.23	9.5	9.4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. John B. Berryman
Director of Regulatory Affairs
American Diagnostics Inc.
222 Railroad Avenue
Greenwich, Connecticut 06830

APR 1 6 2002

Re: k013637
Trade/Device Name: ACTICHROME® Heparin Assay (anti-fIIa)
Regulation Number: 21 CFR § 864.7525
Regulation Name: Heparin Assay
Regulatory Class: II
Product Code: KFF
Dated: March 22, 2002
Received: March 25, 2002

Dear Mr. Berryman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2

STATEMENT OF INDICATIONS FOR USE

Applicant: American Diagnostica Inc.

510(k) Number: K013637

Device: ACTICHROME® Heparin (anti-fIIa)

Indications for Use:

ACTICHROME® Heparin (anti-fIIa) is a chromogenic assay intended for the quantitative determination of therapeutic heparin in human plasma by measurement of factor IIa (thrombin) inhibition. The Electra 900C® was used to determine performance data.

This kit is for *in vitro* diagnostic use.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013637

Concurrence of CDRH, Office of Device Evaluation (ODE)